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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/204,236	12/03/1998	GREGORY S. HAMILTON	AR218-X	5251

29728 7590 10/03/2005

GUILFORD PHARMACEUTICALS C/O
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EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/204,236	HAMILTON ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *90-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *90-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This is a CPA of SN 09/204,236. Claims 1-89 have been canceled. Claims 90-111 are pending. The case has been remanded to the examiner for further evaluation when applicants submit factual evidence with respect to the pending issues.

The following issues remain in the case:

2. Claims 90-111 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-177 of copending Application No. 09/159,105 or continuation/divisional thereof in view of Feghali et al. MEDLINE 98242495. Claims 1-177 of SN 09/159,105 (see WO 99/14998 of 1449) are drawn to treatment of sensorineurotrophic hearing loss which is one of the neurological disorders generically embraced by the instant claims as evidenced by Feghali that sensorineural hearing loss is a neurological disorder treatable by neurotrophic factors. In the instant case, the neurotrophic factors of SN 09/159,105 generically embraced the instantly claimed compounds.

This is a provisional obviousness-type double patenting rejection.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 90-111 are provisionally rejected under 35 U.S.C. 103(a) or under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the reference of the claims of Hamilton et al. US 5,721,256(cited on 1449) or 5,874,449 or 5,968,957 in view of SN 09/159,105 and Feghali et al.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hamilton et al. US 5,721,256, or 5,874,449 or 5,968,957 disclosed and claimed the instant method of treating neurological disorder with neurotrophic compounds. See '256 claim 13, '449, claims 20, 25, 29 and 33, '957 claims 17-20.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Hamilton et al. '256, '449 or '957 disclosed all the elements of the claims **except** the neurotrophic agent are structurally analogous to the claimed compounds. Hamilton et al. SN 09/159,105 (see WO 99/14998, claims 1-177) taught in analogous treating of neurotrophic hearing loss, the '256, '449, '957 compounds/neurotrophic agents are alternative choices for the instantly claimed compounds.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art would be motivated to employ a structurally similar known alternative which have been shown to be successful in treating analogous neurotrophic factor related pathology for the generic neurotrophic factor related pathology as the instant claims. The agent and a reasonable expectation of success are disclosed by Hamilton SN 09/159,105 which would constitute a 102(e) reference when the claims become allowable.

4. Claims 90-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear of what the scope of the claims are. Are they "carboxylic acid" and carboxylic acid isosters ? Or are they including "carboxylate" also. Please note that the cyclic moieties and isosteric structures in claims 90 and 99 included both "carboxylic acid" and "carboxylate" i.e. esters, amides etc. It is clearly known in the art that "carboxylic acid" bioisosteres are distinct from "carboxylate" and the concept has been well taught in the art (see King p.208 carboxylic acid group vs carboxy group and Patani (cited on 892 previously) p.3163-3164 and 3169, especially the concept of corresponding substituents on the ring system of p.3163). the claims included in the term "carboxylic acid isostere" choices of ester and amides are self contradictory and confusing.

5. Claims 90-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton et al. US 5,721,256 in view of King or Patani (cited on 892 previously).

Claims 90-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 5,721,256 in view of King or Patani.

Please note that the claims included both the "carboxylic acid" isosteres and the "carboxylate" isosteres. The "carboxylate" are prima facie obvious over the prior art US 5,721,256. Especially see the species of claim 96, p.6, the 2-ethyl-1,3,4 oxadiazol-5yl

compound is a bioisosteric replacement for '256 claim 13 when E is benzyl, m=0, B=CH3, D=H and the N-alkoxy amido compounds of p.12 are isosteric replacement of the same claim 13 E is benzyl, m=0, B=CH3, D=H, since the amido group is the isostere of carbonyl (see king p.208 carbonyl group).

The replacement of a carboxyl or carbonyl moiety of a biological active compound with a conventional "bioisosteric replacement" is prima facie obvious because artisan in the field is well recognized that such modification is a rational approach in drug design to gain more useful compounds. Such modified compounds under the bioisosterism principle is well recognized to have the same utility as the lead compound i.e. the claimed compounds are expected to be used for the same method as the compounds of claim 13 '256.

6. In the examiner's answer the factual evidence was found to be:

Instant application

SN 09/204,236 *Filing date* 12/03/98 Priority date:60/087,842, 06/03/98

Inventor: Hamilton, Norman, Wu

Assignee: Guilford Pharmaceuticals, Inc/GPI NIL Holdings, Inc.;
AMGEN, Inc.

Claimed scope, subgeneric to SN 09/159,105, compounds and methods fully embraced by claims of SN 09/159,105

Copending application

SN 09/159,105, not yet issued, *Filing date* 09/12/98 Priority date 60/059,905 09/24/97
(see WO 99/14998 submitted on 1449) 60/059,963 09/25/97

Inventor Magal

Assignee: AMGEN, Inc.

Claimed scope, generic to a group of Markush compounds and method of treating neurological disorders using such, fully embraced all the compounds and method of **instant application**.

Evidential application, WO 00/16603
Benefit of SN 09/159,105, not yet issued, Priority date 60/059,905 09/24/97
Filing date 09/12/98 60/059,963 09/25/97

Inventor: Li, Hamilton, Steiner

Assignee: Guilford Pharmaceuticals, Inc/GPI NIL Holdings, Inc.;
AMGEN, Inc.

The above record made it impossible to decide *who owns what at when* because the evidence showee that both Gilford and amgen and three sets of inventors *continuously* filed claims of the same subgeneric subject matter. In accordance with the guidelines set forth in MPEP § 804, a provisional obviousness type double patenting can be withdrawn to let one set of claims become allowable "were the application is the ***first*** of the two copending cases. Applicants are required to clarify the record, of *who owns what at when*, and identify the first case to be issued with filing of appropriate terminal disclaimer for the subsequently filed cases.

7. As all issues stayed the same, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

OACS/Chang
Sept. 29, 2005
Reopen APP. SPE
CTsang

Celia Chang
Primary Examiner
Art Unit 1625